Oral Rabies Vaccine (ORV) – A Primer Adapted from USDA/APHIS/WS

Oral rabies vaccination (ORV) has been under field investigation in the United States since 1990, in Canada since 1985, and in Europe since 1980. Currently there are 15 states distributing oral vaccines for raccoons in the U.S. Raboral V-RG is currently the only effective oral vaccine licensed for use in free-ranging raccoons, gray foxes, and coyotes in the United States.

Raboral V-RG is a genetically engineered vaccinia virus that has been developed by Rhone Merieux, Inc. of Athens, Georgia, to orally vaccinate wildlife against rabies. When the vaccine is given to raccoons through an oral bait, the animals develop protective immunity even when challenged by high doses of virulent rabies virus.

The oral rabies vaccine is produced by splicing the rabies virus glycoprotein gene and inserting it into a non-pathogenic vaccinia virus by genetic manipulation. Thus, the vaccine does not contain live rabies virus and cannot cause rabies. During experimental development, the vaccine was administered to 59 species of mammals and birds without causing problems. Field safety studies have provided more supportive data, and USDA has made a finding of "no significant impact" on the environment associated with this vaccine. During the development and evaluation period, adverse effects relating to the vaccine had not been noted in people who manufactured the vaccine, prepared and distributed the baits (1).

There are rare reports of adverse reactions to V-RG ORV baits in people and animals that have had contact with baits in areas where the baits have been distributed (2, 3). Contact with ruptured baits can produce vaccinia virus infection in certain persons that are at risk including people that are immunocompromised, pregnant, aged <12 years, persons with dermatologic conditions or a history of vaccine exposure to a mucosal membrane. Reports of adverse reactions are typically received through a phone call to the toll free number printed on the vaccine baits when either a human or domestic animal has had contact with the baits. In August 2009, a woman aged 35 years who was taking immunosuppressive medication for inflammatory bowel disease contacted the Pennsylvania Department of Health (PADOH) after handling a ruptured bait. The bait had leaked liquid rabies vaccine onto a patch of abraded skin on her right hand. The patient subsequently developed vaccinia virus infection and was treated with human vaccinia immune globulin intravenous (VIGIV) and an investigational antiviral agent. This was the second case of human vaccinia infection related to ORV bait exposure (2). During the August 23-September 7, 2012 bait drop in Ohio, a total of 504,887 V-RG baits were distributed by automobile in urban areas and by aircraft in rural areas of Ohio over an area of 4,379 square miles. Among 74 V-RG baits found by the population, only two adverse events were reported in dogs that had contact with V-RG baits. The reactions were gastrointestinal upset; the two dogs regurgitated the baits. No adverse events were reported among any of the persons that had contact with V-RG baits, including five persons that had conditions that created a risk for vaccinia infection (3).

The oral rabies vaccine bait consists of liquid vaccine (dyed pink) inside a plastic packet or sachet. The sachet is coated with a thin fishmeal flavoring. The sachet resembles a small ketchup package that contains about 1.5 ml of vaccine. When the raccoon bites into the bait and punctures the sachet the vaccine enters the animal's mouth and coats the lymphatic tissue in the throat. There is an immune response to the rabies antigen which creates antibodies that will prevent the disease if the animal is exposed.

Importantly, children should be instructed to leave the baits alone. Pet owners are asked to supervise their dogs and cats while outside or keep them on leashes to prevent accidental consumption of the baits and to allow raccoons to consume the baits. The baits are smelly and distasteful, so it is not likely that they would be consumed by a person. Nevertheless, the possibility does exist for potential vaccine exposure via bait consumption, or through skin exposure while handling a punctured vaccine packet. It is also possible for vaccine exposure to occur if an animal that recently consumed bait, then, bites a person. Again, there is no danger of getting the disease rabies from exposure to the vaccine packets.

Baits are distributed by fixed-wing airplanes in rural areas and by helicopter in urban and suburban areas. Airplanes fly in straight lines or "transects" at about 500 feet above ground while distributing baits. The bait distribution

machine is controlled from the airplane and is turned off when crossing a road or house to minimize human contact with the bait. Baiting by helicopter in urban and suburban areas (Burnsville, Marshall, Mars Hill, Waynesville and Weaverville) is planned to target raccoons specifically and care is taken to reduce chances of human contact with baits.

- 1, Rupprecht CE, Blass L, Orciari LA, et al. Human infection due to recombinant vaccinia-rabies glycoprotein virus. N Engl J Med. 2001; 345:582-6.
- 2. MMWR Morb Mortal Wkly Rep. 2009 Nov 6;58(43):1204-7.
- 3. MMWR Morb Mortal Wkly Rep. 2013 Apr 12;62(14):267-9.
 - Oral Rabies Vaccine (ORV) homepage
 - Oral Rabies Vaccine Questions & Answers
 - ORV Information for Health and Veterinary Professionals
 - For additional information: USDA Wildlife Services Rabies Management Web site (http://www.aphis.usda.gov/wildlife-damage/rabies)

ORV Questions and Answers

Adapted from USDA/APHIS/WS

What does the bait look like?

For raccoons, the formulation is the coated sachet, which consists of a small packet containing the vaccine, which is then coated in fishmeal and oil. The vaccine (dyed pink) is encased within the white plastic package (sachet) that resembles a fast-food style ketchup or mustard packet. A label printed in black on each bait reads: "RABIES VACCINE / LIVE VACCINIA VECTOR / DO NOT DISTURB / 1-877-722-6725.

Q: What if I find a bait near my home?

A: It is best to leave the bait where you found it unless it is on your lawn, driveway, or other area not likely to attract a raccoon or is in an area frequented by children or pets. While wearing a rubber or latex glove, you can move the bait to an area of thicker cover, away from children and pets, where a raccoon will be more likely to find it. Wash your hands thoroughly with soap and water after any contact with a bait.

Q: Why do I need to wear a rubber or latex glove when handling a bait?

A: An intact bait will not harm you but the smell may get on your skin and is objectionable to people. If a bait is broken and pink liquid (vaccine) is visible, while wearing gloves you may place the bait in a bag and dispose of it with your regular trash because the bait will no longer be effective. Wash your hands thoroughly with soap and water after any contact with a bait.

Q: What if my child finds a bait?

A: The smell of the bait generally prevents children from playing with or tasting them. If your child were to bring you an intact bait, you may place the bait into an area of thick cover; if your child brings you a broken bait, wash the exposed skin and call the U.S. Department of Agriculture's Wildlife Services office at 1-866-4 USDA-WS (1-866-487-3297), for further instructions and referral.

Q: What if my dog or cat eats a bait?

A: This vaccine has been shown to be safe in over 50 different species of animals, including domestic dogs and cats. Eating a large number of baits may cause a temporarily upset stomach in your pet but does not pose a long-term health risk. Do not attempt to remove a bait from your pet; doing so may cause you to be bitten.

Q: Can I get rabies from contact with the vaccine?

A: No. The vaccine does not contain the live rabies virus, but only a single gene from the outer coating of the rabies virus. However, the vaccinia virus that carries this single rabies gene may cause a local pox-type infection in people who are pregnant or have an immunodeficiency disease. If you come into contact with the vaccine, wash the affected area thoroughly with soap and water and call the U.S. Department of Agriculture's Wildlife Services office at 1-866-4 USDA-WS (1-866-487-3297), for further instructions and referral.

Q: How does a raccoon get vaccinated by eating this bait?

A: The vaccine is contained inside a plastic packet that is coated with fishmeal. When a raccoon bites the bait, the vaccine packet is punctured and the vaccine gets into the animal's mouth. The raccoon's immune system is then tricked into thinking it has been exposed to the rabies virus and makes antibodies to fight the disease. The "blueprint" on how to make these antibodies is then stored in the raccoon's immune system, allowing its body to respond quickly should it be exposed to a rabid animal.

Q: Can I use this bait to vaccinate my dog or cat?

A: No. This vaccine is only approved for use in wildlife. Your pet should be vaccinated by a veterinarian in accordance with state and local laws. If you have questions about vaccinating your pet, contact your local Animal Control or the N.C. Veterinary Public Health Program at 919-733-3419 or by e-mail (vetpublichealth@ncmail.net).

Q: How are baits distributed?

A: In rural areas, baits are dropped from fixed-wing airplanes. Baits are distributed in urban and suburban areas (Burnsville, Marshall, Mars Hill, Waynesville and Weaverville) by helicopter. This is done to get the most effective bait distribution and to minimize human contact with baits.

Q: Why should I be worried about rabies in wildlife?

A: Rabies in wildlife is a serious public health concern because infected wild mammals can transmit the rabies virus to domestic animals and to people. If left untreated in animals or people, rabies is always fatal. Costs associated with detection, prevention and control of rabies exceed \$300 million annually. According to the Centers for Disease Control and Prevention (CDC), about 90 percent of reported rabies cases are in wildlife.

Q: How can I find out more information about this program?

A: You can dial **1-866-4 USDA-WS** (1-866-487-3297) to speak with staff from the United States Department of Agriculture Animal and Plant Health Inspection Service's Wildlife Services national rabies management program, or visit their web site at http://www.aphis.usda.gov/wildlife-damage/rabies

Q: What are the dangers of ORV to humans and other animals?

A: The vaccine and bait are not considered to be dangerous. The bait coating is made of fishmeal mixed with a nontoxic bonding agent; tetracycline is added as a biomarker. The bait poses no danger to human or animal health.

Extensive research in a wide variety of species has shown the oral rabies vaccine inside the packet to be very safe. The vaccine is made by utilizing the most current technology, and only non-infectious portions of the rabies virus are used. Therefore, neither humans nor animals are in danger of developing rabies if they are exposed to the vaccine.

A domestic animal's annual rabies vaccination can be safely administered even if the animal recently ingested a dose of the oral rabies vaccine. However, when people are exposed to the vaccine, it is advised that physicians consider the possibility of complications due to exposure to vaccinia, particularly if the person is immunocompromised or has dermatological conditions such as eczema. However, such reactions are rare.

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